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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/414,091      | 10/07/1999  | STAVROS C. MANOLAGAS | D6210               | 2781             |

7590 02/03/2003

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| EXAMINER |
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CRIARES, THEODORE J

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| ART UNIT | PAPER NUMBER |
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1617

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DATE MAILED: 02/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/414,091

Applicant(s)

MANOLAGAS ET AL.

Examiner

Theodore J. Criares

Art Unit

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-- Th MAILING DATE of this communication app ars on the cov r sh et with the correspond nce address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6, 7, 9, 10 and 13-37 is/are pending in the application.
- 4a) Of the above claim(s) 1, 3, 4, 6, 7, 10 and 13-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 2 and 9 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**CLAIMS 1-4, 6, 7, 9, 10, AND 13-37 ARE PRESENTED**  
**FOR EXAMINATION**

Applicant's election without traverse of Group I, claims 2 and 9 in Paper No. 18 is acknowledged.

Further restriction is required.

Applicants' claims are drawn to the treatment of bone with a non-estrogenic agent. The claims to be examined will be 2, and 9 since claim 5 has been canceled.

A careful reading of the specification teaches the administration of an astronomical number of compounds classified throughout classes 514 and 424 which have established separate and distinct status in the pharmaceutical art. The claims to be examined read on a broad class of compounds under the phrase "non-estrogenic agents". For example applicants specification teaches non-estrogenic agents as, bisphosphonates, classified in class 514, subclass 108; teriparatide amino acid fragments classified in class 513, subclass 12+; calcium preparations classified in class 424, subclass 422, etc.

An undue burden will be placed on the examiner in the search of the patent literature since a search, as exemplified above, has to be conducted in both the organic in addition to the inorganic arts. This is further illustrative that the claims are separate and distinct.

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It would be helpful in the search if applicants provide the examiner with compounds within the class and subclass which is to be searched. e.g., bisphosphonates, Vitamin D , parathyroid hormone

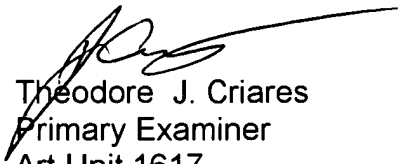
Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Further restriction may be required.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Criares whose telephone number is 308-4607. The examiner can normally be reached on 6:30 A.M. to 5:00P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-6897 for regular communications and N/A for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1235.

  
Theodore J. Criares  
Primary Examiner  
Art Unit 1617

tjc  
January 30, 2003